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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,417	08/22/2001	Leon V. Rudakov	52200-8006.US01	9486

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,417	RUDAKOV ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 is rejected under 35 U.S.C. 102(e) as being anticipated by Alcime et al., 5,632,772.

As to claims 17 and 18, Alcime discloses an expandable support (stent, for example, reference 32, column 6, line 48) from having first and second end portions, a porous polymer sleeve (liner, for example, reference 34, column 6, line 53-55) having inner and outer surfaces, and a coating of a cell adhesion peptide (column 13, lines 56-61) carried on and attached to at least one of the inner and outer surfaces of the polymer sleeve for enhancing endothelial cell growth on the polymer sleeve.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alcime et al., 5,632,772, in view of Bhatnagar, 5,958,428.

Claim 18 is a product by process claim so no weight is given to the process limitations. The product is substantially disclosed by Alcime (see above.) Additionally, Alcime teaches that the stent is made of metal (col. 13, line 18 and 24.) However, Alcime does not specifically disclose linkers/spacers forming covalent bonds with the cell-adhesion peptides as a means to link the peptides to the substrate.

Bhatnagar discloses use of spacer arms to facilitate binding of peptides to a substrate, including glass, plastics, and metallics, (col. 10, lines 24-32, and lines 51-53.) It would have been obvious to one of ordinary skill in the art to provide spacers/linkers as taught by Bhatnagar in order to link the peptides to the metallic Alcime substrate, as a well known and conventional means of attaching biomolecules to a substrate.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alcime et al., 5,632,772, in view of Brown et al., 6,071,305, and further in view of Bhatnagar, 5,958,428.

Alcime et al. disclose the invention substantially as claimed (see above), except for the cell-adhesion peptide having the amino acid sequence presented as SEQ ID NO:1. Alcime teaches an expandable stent for treatment of blood vessels, wherein the stent includes therapeutic drugs such as heparin, column 13, lines 56-61.

Brown et al. teaches the use of therapeutic drugs such as heparin or collagen on a stent (column 2, lines 38-52, column 5, line 17 and 26).

Bhatnagar teaches that collagen functions as a structural protein of tissues and that it is the major fibrous element in blood vessels, see column 1, lines 50-53, and that collagen participates in physiological interactions which include formation of complexes with other macro-molecules such as fibronectin and the modulation of cell proliferation, see column 2, lines 24-31. Bhatnagar further discloses that collagen appears to cause adverse reactions within the body, and thus synthetic peptides are provided that mimic the cell binding domain of collagen, see column 3, lines 21-32. Bhatnagar teaches that the synthetic peptide has the amino acid sequence as disclosed in column 3, lines 42-43, which is the same amino acid sequence as Applicant's claimed SEQ ID NO:1.

Since both Alcime and Brown both teach the use of providing a therapeutic drug such as heparin or other drugs on a stent, and Brown further teaches that the drug may also be collagen, it would have been obvious to provide collagen as the therapeutic drug in the Alcime stent with the polymer sleeve.

Furthermore, it would have been obvious to provide, on the Alcime stent, the synthetic peptide disclosed by Bhatnagar, as an alternative to collagen, as would be desirable to obtain the same therapeutic effect as collagen but without the adverse effects of collagen, as taught by Bhatnagar.

Response to Arguments

Applicant's arguments filed April 27, 2005 have been fully considered but they are not persuasive.

Applicant argues on page 4 that there is no teaching or suggestion that the drugs recited by Alcime et al. enhance endothelial cell growth and that a "coating...for enhancing endothelial cell growth" is also not "necessarily present" in the reference.

Examiner notes that as to claim 1 Applicant has not specifically recited a particular drug. Rather, Applicant recites "a cell adhesion peptide.....for enhancing endothelial cell growth". The drugs listed by Alcime include heparin for example. Heparin is capable of enhancing endothelial cell growth and thus meets the claim. (See for example, Hubbell et al., 6,894,022, column 2, lines 41-44, which teaches that heparin induces cell in-growth and tissue regeneration. Collins et al., 5,434,185, column 9, lines 64-67, teaches that heparin-like substances promotes endothelial cell growth.)

Applicant also argues on page 6 that as to claim 18, neither Bhatnagar nor Alcime teach a plasma deposited layer having functional groups that have covalently attached thereto multifunctional linkers/spacers to covalently bind a cell adhesion peptide.

Examiner reasserts that Bhatnagar teaches use of spacer arms to facilitate binding of peptides to metallic substrates (such as the Alcime metallic stent). The "plasma deposited" part of claim 18 is examined as if it is a product-by-process limitation. Thus, the prior art meets the limitation if it discloses the product. The Bhatnagar disclosure meets the limitation because it discloses "linkers/spacers".

Applicant also argues on page 7 that as to claim 19, Brown et al. teaches away from the claimed invention because Brown et al. teaches that the agent resides in the cavity of a stent. Applicant also argues that there is no teaching or suggestion that the

graft of Alcime et al. should be modified to include a coating of the peptide described in Bhatnagar because Alcime et al. does not teach or suggest use of a "coating...for enhancing endothelial cell growth".

In response, Examiner reasserts that the motivations to combine the references are taught by Brown et al. in teaching that a stent may include therapeutic drugs such as collagen (as an alternative to, for example, heparin) and Brown et al. in teaching that a synthetic collagen provides the advantages of the therapeutic affects of collagen without the adverse reactions within the body.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hubbell et al., 6,894,022, column 2, lines 41-44, which teaches that heparin induces cell in-growth and tissue regeneration. Collins et al., 5,434,185, column 9, lines 64-67, teaches that heparin-like substances promotes endothelial cell growth.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~/641
5/25/05